DEC 21 2000

K003248

Special 510(k): Device Modification
SIEMENS Medical Information Bus (MIB) Protocol Converter

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: October 12, 2000

Trade Name, Common Name and Classification Name:

A. Trade Name:
Siemens Medical Information Bus (MIB) Protocol Converter

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Transducer Signal amplifier and conditioner	73 DQA	II	21 CFR 870.2060

Legally Marketed Device Identification:
Siemens Medical Information Bus (MIB) Protocol Converter: 510(k) K923682, K973222, K991661.

Description of Modification:
The Medical Information Bus (MIB) Protocol Converter has received three 510(k) clearances.

1. 510(k) K970368 was cleared for interface with Siemens SV300 ventilator and the Baxter Vigilance blood gas/continuous cardiac output monitor.
2. 510(k) K973222 was cleared for interface with Puritan Bennett 7200 ventilator, the Draeger Evita II, Draeger Evita IV, and Draeger Babylog ventilators, and Siemens SV900 ventilator.
3. 510(k) K991661 was cleared for interface with
   Anesthesia Systems
   Dräger Narkomed II Dräger Narkomed IV Dräger Julian Ohmeda 7900
   Point of Care Blood Gas Analyzers
   Abbott Oximetrix 3
   AVL Medical Instruments
   Opti Critical Care Analyzer, Portable Blood Gas Analyzer
   Optical Sensors Inc.
   OSI – Optical CAM
   VIA Medical
   VIA V-ABG1 Blood Gas Chemistry Monitor

Minor software modifications have been made to Siemens Medical Information Bus (MIB) Protocol Converter and a device specific accessory cable is now available that allows an interface connection for the Aspect A-2000 BIS Monitor to the INFINITY modular monitors (SC7000/SC9000XL/SC8000).

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16 Electronics Avenue
Danvers, MA 01923
USA
Tel: (978) 907-7500
Fax: (978) 750-6879
Telex: 511958 (Siemensm SD)

Intended Use:
The Siemens Medical Information Bus (MIB) Protocol Converter is intended for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that a third party medical device that provides data, such as: Siemens SV 300 ventilator, Baxter Vigilance blood gas/continuous cardiac output monitor, Siemens SV900 ventilator, Draeger Evita II ventilator, Draeger Evita IV ventilator, Draeger Babylog ventilator, Puritan Bennett 7200 ventilator, Draeger Narkomed II Anesthesia System, Draeger Narkomed IV Anesthesia System, Draeger Julian Anesthesia Machine, Ohmeda 7900 Anesthesia Machine, Abbott Oximetrix 3 Blood Gas Analyzer, AVL Medical Instruments: Opti Critical Care Analyzer Portable Blood Gas Analyzer, Optical Sensors Inc.: OSI – Optical CAM, VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor; Aspect A-2000 BIS Monitor should be connected to a Siemens INFINITY Modular Monitor for display.

Assessment of non-clinical performance data for equivalence: Section K

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: 1073.3.1 – 1994 IEEE Standard for Medical Device Communications Transport Profile – Connector Mode
1073.4.1 – 1994 IEEE Standard for Medical Device Communications Physical Layer Interface – Cable Connected

COMPANY CONFIDENTIAL

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2000

Ms. Penelope Greco
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K003248
Trade Name: Siemens Medical Information Bus Protocol Converter
Regulatory Class: III (three)
Product Code: MHX
Dated: November 20, 2000
Received: November 24, 2000

Dear Ms. Greco:

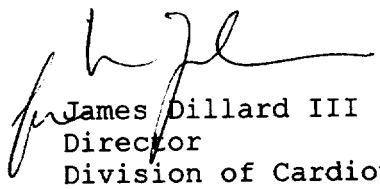
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Siemens Medical Information Bus (MIB) Protocol Converter

Indications for Use:

The Medical Information Bus (MIB) Protocol Converter is indicated for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that third party medical devices that provide data, such as:

Siemens SV 300 ventilator
Baxter Vigilance blood gas/continuous cardiac output monitor
Siemens SV900 ventilator
Draeger Evita II ventilator
Draeger Evita IV ventilator
Draeger Babylog ventilator
Puritan Bennett 7200 ventilator
Draeger Narkomed II Anesthesia System
Draeger Narkomed IV Anesthesia System
Draeger Julian Anesthesia Machine
Ohmeda 7900 Anesthesia Machine
Abbott Oximetrix 3 Blood Gas Analyzer
AVL Medical Instruments: Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Optical Sensors Inc.: OSI – Optical CAM
VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor
Aspect A-2000 BIS Monitor

should be connected to a Siemens INFINITY Modular Bedside Monitor (SC 7000 / SC 8000 / SC 9000XL) for display.

MRI Compatibility Statement:
The Medical Information Bus (MIB) Protocol Converter is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003248